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10/045,803	01/12/2002	Philip Connolly	7287	3678

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EXAMINER	
HENDRICKS, KEITH D	

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/045,803	Applicant(s) CONNOLLY, PHILIP
	Examiner Keith Hendricks	Art Unit 1761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7,8 and 10-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7,8 and 10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 7-8 and 10-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 7-8 and 10-18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The amount of protein administered in the claims is dependent upon the amount of "total daily consumption of protein by the subject", as well as the amount of protein contained in the "combination of milk protein concentrates and probiotic bacteria." None of the three amounts are provided, yet in order for one skilled in the art to determine the metes and bounds of the claimed invention, all three must be known. Even if a total amount of protein were provided in the claims regarding that contributed by the milk concentrates and the bacteria, this still would not provide how much is to be "administered" (which is what is actually claimed) as a percentage of the "total daily consumption of protein by the subject", since the total daily consumption is variable and indeterminable from the claims.

Again, claims 11 and 15 are indefinite due to the recitation of the phrase "containing *Bifido* bacteria and lactic acid producing bacteria". *Bifido* bacteria are lactic acid-producing bacteria, and thus the metes and bounds of the claimed invention are unclear. It is unclear if the limitations of the claims would be satisfied by (a) two of the same *Bifido* bacteria, (b) two different species of *Bifido* bacteria, or only by (c) a *Bifido* bacteria and another non-*Bifido* bacteria genus/species of lactic acid-producing bacteria.

Again in claim 17, it is unclear as to the distinction between *Lactobacillus acidophilus* and some other "*Acidophilus* bacteria". Further, it appears that the claim includes Acidophilus bacteria in both parts (B) and (C), and thus the metes and bounds of the claimed invention are unclear.

Again, the use of the percentages "0.1% to 1%" in claims 17 and 18, is indefinite, as it is unclear as to what whole entity these percentages pertain. To contrast, the percentage "65% to 90%" appears to pertain to the milk protein within the milk ingredient; however, the percentages of the bacteria are unclear, in relation to the whole (0.1% to 1% of what?). Further, this is disjointed from the recitation of the number of microorganisms per gram of milk protein concentrate, as it is unclear as to how one skilled in the art is to determine the amount of microorganisms to utilize in the product. The percentages of "65% to 90%" and "0.1% to 1%" (three times) do not add to 100% of a total amount of a composition. Further, the correlation for each microorganism of "0.1% to 1%" of a total, to a total of 100,000 to 50,000,000 microorganisms, is unclear. It is unclear as to how these numbers are to both be achieved by one skilled in the art.

New Rejection:

The phrase "increase the subject's total daily consumption of protein to approximately 1.5 grams to approximately 4.0 grams" is indefinite for two primary reasons:

1. This phrasing does not provide one skilled in the art with an actual amount to be administered, as the original starting amounts of protein within a subject will vary with each individual. Thus, the metes and bounds of the claimed invention are unclear.
2. The phrase "to approximately 1.5 grams to approximately 4.0 grams" is vague and indefinite, as it does not set forth whether this is either an actual range, or if these are two specific amounts from which one skilled in the art must select.

Claim Objections

Claims 1-2, 7, 10 and 16-17 are objected to because of the following informalities. Appropriate correction is required.

- Claims 2, 7 and 16 (at the least) improperly contain a period (.) in the middle of the claim, after "*Lactobacillus plantarum*".
- Claim 17, part (C), the spelling of "Lactobacillus Bulgarious" should be "Lactobacillus bulgaricus". See for example, claim 2.
- In claims 1, 7 and 10, each within the portion added via amendment, the phrase "to increase the" improperly appears twice consecutively.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

i) Claims 11-18 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Meister et al. The reference and rejection are taken as cited in a previous Office action.

Applicant's arguments filed July 16, 2003, have been considered, but are not deemed persuasive.

At pages 14-16 of the response, applicants generally state that the reference does not teach various added limitations of the amended claims. However, applicant fails to clearly and specifically state how the reference fails to demonstrate the claimed invention. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

At page 16 of the response, applicant states Meister et al. do not teach or suggest that the steps "include filtering milk to remove non-protein constituents of milk." This is not deemed persuasive for the reasons of record. As previously stated on the record, regarding the second two steps of instant claim 11 ("filtering" and "discontinuing"), these are simply techniques for forming concentrated milk, and the last step of "inoculating" is simply a known culturing technique to create the lactic acid bacteria cultures. These do not appear to contribute an inventive step to the claims, *per se*. Regarding the steps of inoculating the filtered/concentrated skim milk with the bacteria, these steps were known and taught by the reference as well. Meister et al. utilizes a concentrated skim milk, and the step of filtering the skim

milk was a well known and art-recognized technique, known as ultrafiltration, for forming said concentrated milk. This is the same filtration technique as that utilized by applicant; see the top of page 11 of the specification. The well-known steps of producing concentrated milk (via ultrafiltration) would thus inherently remove the non-protein constituents of milk. This known step of forming the known product does not appear to be the crux of applicant's invention, and does not appear to contribute an inventive step to the claims.

ii) Claims 1-2, 7 and 10 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bohren.

The reference and rejection are taken as cited in a previous Office action.

Applicant did not traverse this rejection, and this it remains for the reasons of record.

iii) Claim 1 remains rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of the following: Kronberg, Jameson et al., Nielsen, or Kosikowski et al.

The reference and rejection are taken as cited in a previous Office action.

Applicant did not traverse this rejection, and this it remains for the reasons of record.

Claim Rejections - 35 USC § 103

Claims 1-3, 7-8 and 10 are rejected under 35 U.S.C. 103(a) as obvious over Meister et al. The reference is taken as cited in a previous Office action. The claims were previously cited as rejected under both 35 U.S.C. 102(b) as anticipated by, in the alternative, under 35 U.S.C. 103(a), as obvious over Meister et al.

As Meister et al. disclose a process for producing a dehydrated *food composition*, it would have been simple and obvious for one of ordinary skill in the art to have administered this food composition to a human subject, thus satisfying the actual method steps of the claimed invention. Thus, this is clearly suggested by the reference.

* This rejection maintains the applicable portion of the previous prior art rejection under 35 U.S.C. 102(e) or in the alternative, under 35 U.S.C. 103(a). Note the previous statements on the record regarding the lack of clarity of the claims and the difficulty in assessing the metes and bounds of the claimed invention in order to compare such to the prior art of record.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano, can be reached at (703) 308-3959. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3602.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

KEITH HENDRICKS
PRIMARY EXAMINER